Patent US 205C2

Attorney Docket: RMI-5723 CON2

(formerly 271/094)

## REMARKS

Reconsideration of the rejections set forth in the Office Action mailed January 25, 2005, is respectfully requested. Claims 1-3, 6-12 remain pending in this case.

## Art Rejections

Claims 1-3, 6-10, and 12 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Bajaj (USP 5,053,008) in view of Kletschka (USP 4,794,928). The examiner has taken the position that "[i]t would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Kletschka to modify the upstream member of Bajaj by making it a sealing member for creating a seal between the upstream end of the expandable conduit and internal wall of the body passage without causing any trauma thereto in order to prevent substantially all physiologically significant particles from escaping an obstruction site and remove substantially all potential embolic material."

Applicants respectfully assert that neither Bajaj nor Kletschka teach or suggest a catheter apparatus having "an expandable conduit." A "conduit" is, according to its plain and ordinary meaning, generally understood to require a pipe or a tube, i.e., open at both ends. This definition is consistent with the description in both the present application (See Figs. 1, 2, 3, 9, and 13) and Macoviak, U.S. Patent No. 6,254,563 (See Figs. 1, 4, 5, 7, 9a, 10a, 11a, 12a, 13, 15, 17, and 20), from which the present claims were copied. Both Bajaj and Kletschka, by contrast, employ structures having a conical element that expands at the distal end of a catheter. Even if the base of the cone were considered to be one opening, the structures of Bajaj and Kletschka are closed at the opposite end, and therefore, cannot properly be considered a "conduit." Therefore, the asserted combination of references fails to produce the claimed invention.

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Applicants moreover respectfully assert that there is no motivation or incentive to combine the cited references. Bajaj is concerned with use of an umbrella filter assembly connected at one end to the outer diameter of the catheter and at its other end to the inside diameter of a tubular balloon. Bajaj repeatedly emphasizes the importance of minimizing the amount of pressure that the balloon exerts on the pulmonary trunk wall. (See, e.g., Col. 6, lines 11-15). "The balloon 20 primarily serves the function of acting as a cushion for the pulmonary artery endothelium 30 and is preferably made of a soft expansible material so as to minimize trauma." (Col. 8, lines 44-47) Additionally, Bajaj teaches that "[b]y manipulating the tension control syringe 32, the physician can adjust the degree of opening of the umbrella 18 so that the balloon 20 barely touches the wall 30 of the pulmonary trunk, thereby reducing the pressure on the wall 30, yet fully encircles and hugs the wall 30." (Col. 8, lines 17-22, emphasis added) Furthermore, Bajaj states that "[i]deally, the pressure in the balloon 20 should be just enough to maintain it in an expanded state and provide a cushioning affect against the wall 30." (Col. 8, lines 32-34) As repeatedly emphasized, the main function of the balloon is to reduce the pressure of the umbrella filter against the pulmonary artery by providing a cushioning effect, not to provide a seal in order to prevent the passage of substantially all physiologically significant particles. No such seal is ever contemplated by Bajaj. On the contrary, Bajaj contemplates movement of the umbrella filter and the cushioning effect of the balloon that is thought to minimize any transmitted force on the vessel walls. (See Col. 8, lines 34-37, "Hence, if there is any movement of the umbrella 18 caused by blood flow, the transmitted force from the blood flow is minimized.") Bajaj does not recognize any problem with any embolic material escaping the filter. Rather, Bajaj describes a system that is concerned with capturing relatively large embolic material greater than 3 mm in size. (See Col. 7, lines 60-63, "the meshwork is loose enough to allow the free flow of blood and plasma therethrough, but obstructs larger objects, i.e.,

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greater than 3 mm in size.") Therefore, there is no motivation to combine the teachings of Bajaj and Kletschka.

Additionally, Kletschka describes a system in which the trap/barrier membrane is forming a seal with the vessel wall. (See, e.g., Col. 8, lines 52-62) There is no separate sealing member as described in Bajaj. Therefore, at best, the combination of Bajaj in view of Kletschka would suggest that the umbrella filter would form a seal with the vessel wall.

## FEES DUE TO FILE THIS AMENDMENT

Prior to the pending Office Action, a fee was paid for the original 23 claims, with 3 of them being independent claims. The aforementioned claim additions and cancellations have not resulted in more than the original number of claims, and thus no claim fees are believed to be due to file this amendment.

## PETITION FOR EXTENSION OF TIME TO RESPOND

Pursuant to 37 C.F.R. 1.136(a), Applicants hereby request an extension of time for Two (2) Months to respond to the above-referenced Office Action. The Commissioner is hereby authorized to charge the required fee of \$450.00 to Deposit Account No. 50-1225 (Docket No. RMI-5723CON2). A duplicate copy of this sheet is enclosed.

For the above reasons, pending Claims 1-3 and 6-12 are in condition for allowance and allowance of the application is hereby solicited. If the Examiner has any questions or concerns, a telephone call to the undersigned at 949-250-6856 is welcomed and encouraged.

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fully submitted.

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